

CLAIMS

What is claimed is:

1. A method for monitoring temporal changes of analyte levels in a source comprising:

providing multiple test devices, each including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;

5 bringing a sample from the source into contact with a first of the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more of the test unit regions;

subsequently bringing a different sample from the source into contact with a second of the test devices to determine whether the source contains a level of analyte
10 sufficient to induce a response thereto in one or more regions of the second test device, said responses providing information about temporal change in analyte concentration.

2. A rapid assay concentration device comprising:

a substrate

a plurality of elongated membranes, of the type which exhibit capillary flow of
15 fluid therethrough, positioned on the substrate; and

at least one capture zone formed in each membrane, each said one capture zone responsive to the presence of a target chemical in the fluid and entering said one zone, capture zones on different membranes having different threshold levels of response to the chemical.

20 3. The device of claim 2 wherein each membrane has a different porosity than the other membranes.

4. The device of claim 2 wherein the capture zones provide an immunocomplex when the chemical is present therein.

5. The device of claim 2 wherein each capture zone develops a visually detectable response when a predetermined threshold level of the chemical is in the fluid.

6. The device of claim 2 further including a sample region for receiving the fluid,
5 a conjugate pad positioned to transmit the fluid from the sample region to at least one of the membranes, and an absorbing medium positioned on the substrate to receive fluid from at least one of the membranes.

7. A rapid assay concentration device for analyzing a target analyte in a fluid sample, comprising:
10 a substrate; and
an elongated test membrane having multiple spaced-apart capture zones formed thereon, each positioned to provide a different sensitivity response to the presence of analyte in the source.

8. The device of claim 7 further including a sample region for receiving the fluid,
15 a conjugate pad positioned to transmit the fluid from the sample region to the membrane, and an absorbing medium positioned on the substrate to receive fluid from at least one of the membranes.

9. The device of claim 7 wherein the position and relative sensitivity of each capture zone to the other capture zones is primarily a function of flow rate characteristics
20 of the fluid through the membrane.

10. A method for monitoring changes in analyte level of a source, comprising: defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;
providing a first test unit including a first region thereon responsive to the
25 presence of analyte in the source at a first of the sensitivity levels;
providing a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the source;

bringing the first sample into contact with the first unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the first level;

5 providing a second sample from the source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the second level.

10 11. The method of claim 10 wherein the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes providing said second region an opportunity to indicate presence of analyte in the sample at at least the second level.

15 12. The method of claim 10 wherein the first unit includes a second region responsive to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes providing said second region an opportunity to indicate presence of analyte in the sample at at least said one sensitivity level different than the first of the sensitivity levels.

20 13. The method of claim 10 wherein said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels.

25 14. The method of claim 10 wherein the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels.

15. The method of claim 10 wherein the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the measurably distinguishable sensitivity levels.

5 16. The method of claim 15 wherein the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the measurably distinguishable sensitivity levels.

10 17. The method of claim 16 wherein the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level.

18. The method of claim 16 wherein each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit.

15 19. The method of claim 10 wherein the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions.

20 20. A method for monitoring changes in analyte level of a source, comprising:
providing two or more test units each including multiple regions thereon, each region responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from the other;

bringing a first sample from the source into contact with a first of the units to provide one or more of the regions thereon an opportunity to indicate presence of the analyte in the sample at at least one of the levels; and

25 on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to provide one or more of the

regions thereon an opportunity to indicate presence of the analyte in the second sample at at least one of the levels.

21. The method of claim 20 wherein the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate.

5 22. A test device for determining whether a liquid sample contains analyte within one of several measurable ranges, comprising:

a substrate; and

10 a plurality of distinguishable regions each positioned on the substrate and coupled to receive a portion of the sample, each region capable of generating a visually discernable signal in response to a minimum level of analyte in the sample.

23. The unit of claim 22 wherein the regions are distinguishable based on the concentration of a reactive chemical present in each region.

24. A test unit for determining whether a sample contains analyte within one of several different ranges, comprising:

15 a substrate;

a plurality regions each chemically responsive to the presence of analyte in a different range; and

20 a plurality of lanes each coupled to receive chemical from one of the regions and indicate when at least a minimum level of analyte is present in the region by generating a visually discernable signal in response thereto.